MAY 18 2010

Summary of Safety and Effectiveness

Submitter:
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Date Prepared: May 13, 2010

Device: Cardo Medical Ceramic Hip System

Classification: 87 LZO - prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented, 21 CFR 888.3353 Class II

Predicate Device: Accin™ Hip System (now Cardo Medical Hip System) - K073068, K094045
Stelkast 32mm Modular Ceramic Head – K033944

Device Description: The previously cleared Cardo Medical Hip System consists of

- commercially pure titanium plasma spray-coated titanium alloy (Ti-6Al-4V) femoral stems,
- cobalt chrome (CoCr) femoral heads,
- commercially pure titanium plasma spray-coated titanium alloy (Ti-6Al-4V) acetabular shells,
- ultra-high molecular weight polyethylene (UHMWPE) acetabular inserts, and
- titanium alloy (Ti-6Al-4V) bone screws.

The proposed devices are a line extension to the previously cleared system to add 32mm and 36mm alumina ceramic femoral heads.

Intended Use: The Cardo Medical Ceramic Head components are for use in total hip arthroplasty as a result of:

- Hip arthritis caused by rheumatoid disease, non-inflammatory degenerative joint disease, osteoarthritis, and arthritis resulting from biologic or mechanical trauma to the hip,
- Correction of functional deformity,
- Avascular Necrosis,
- Treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur,
- Difficult clinical management problems involving persistent pain and physical impairment where conventional arthodesis is not likely to achieve satisfactory results.

These components are single use only and are intended for implantation with or without bone cement.

Comparison to Predicates:
The Cardo Medical Ceramic Heads are manufactured from alumina ceramic and are for use with the currently marketed femoral stem, acetabular shell, acetabular inserts and bone screws. The proposed devices are similar in design and materials to the Cardo Medical Total Hip System (K073068 and K094045) and the Stelkast Ceramic Heads (K033944).

Femoral Stems
There has been **no change** to the existing femoral stems.

K100008

Femoral Heads
The proposed alumina ceramic femoral heads have the same 12/14 trunnion taper as the previously cleared cobalt chrome femoral heads, offered in sizes 22 through 36 mm OD in a variety of offsets (K073068 and K094045) and are equivalent in size, design, packaging, and sterilization. They are equivalent in material to the Stelkast ceramic femoral heads.

Acetabular Shells
There has been **no change** to the existing acetabular shells. They are designed to mate with the acetabular inserts and have holes for bone screws, if necessary.

Acetabular Inserts
There has been **no change** to the existing UHMWPE acetabular inserts, offered in sizes 22 through 36mm. They are designed to mate with the previously cleared acetabular shells.

Bone Screws
There has been **no change** to the existing titanium alloy bone screws cleared in K073068, which are in a 6.5mm diameter, in lengths from 15mm to 60mm.

All Cardo medical implant components are provided as sterile, single use only to a sterility assurance level (SAL) of 10^{-6}.

Summary
Cardo Medical, Inc. has determined that any differences in the proposed device will not impact the safety or effectiveness of the hip system for its intended use. Testing has shown that the proposed device meets the requirements of the FDA Guidance document "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems" and the guidance on total hip arthroplasty. The proposed device is substantially equivalent to the predicate device.

Synopsis of Test Methods and Results:

Nonclinical Performance
All mechanical testing required by the guidance document for ceramic heads is included in this submission including technical reports for stem fatigue mechanical testing; the push-in, push-out, lever-out and rotational torque forces for acetabular inserts; the Range-of-Motion (oscillation) of the proposed system; and static burst testing, dynamic fatigue testing and Axial Pull-Off testing of the femoral heads. Results indicate that the Cardo Medical ceramic femoral heads and inserts is equivalent to devices currently legally marketed, is compatible with the previously cleared 12/14 femoral heads and capable of withstanding *in vivo* loading.

Clinical Performance
Clinical data and conculsions are not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cardo Medical Inc.
% Ms. Dina Weissman, J.D.
Director, Quality Assurance,
Regulatory Affairs and Government
10 Clifton Boulevard, Suite B1
Clifton, New Jersey 07011

MAY 18 2010

Re: K100008
Trade/Device Name: Cardo Medical Hip System
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Regulatory Class: II
Product Code: LZO
Dated: April 30, 2010
Received: May 3, 2010

Dear Ms. Weissman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K100008

Device Name: Cardo Medical Hip System

Indications for Use:
The Cardo Medical Hip System components are for use in total hip arthroplasty as a result of:

- Hip arthritis caused by rheumatoid disease, non-inflammatory degenerative joint disease, osteoarthritis, and arthritis resulting from biologic or mechanical trauma to the hip
- Correction of functional deformity
- Avascular Necrosis
- Treatment of non-unions, femoral neck and trochanteric fractures of the proximal femur
- Difficult clinical management problems involving persistent pain and physical impairment where conventional arthodesis is not likely to achieve satisfactory results

These components are single use only and are intended for implantation with or without bone cement.

Prescription Use ___X___ OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100008